REMARKS

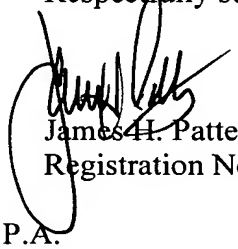
Claims 10-21 are pending. By this Amendment, claims 1-9 are cancelled and new claims 10-21 are added.

The present application has been translated from the original French. The specification, abstract, and claims have been amended herein to more closely conform to customary U.S. practice. No new matter has been added and no narrowing amendments are intended.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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DEVICE FOR CONNECTION BETWEEN A CORPOREAL DUCT AND A PROSTHESIS

Related Application

This application claims priority to PCT Application No. PCT/FR2003/002988 filed October 10, 2003, which claims priority to French Application No. 02/12601 filed October 10, 2002.

Field of the Invention

This invention concerns the placement of a tubular prosthesis attached, either to the end of a body duct or between two body ducts to be joined, by intubation of one or both of the extremities of the prosthesis in the body duct or ducts and the fixation of the intubed parts with the aid of a connecting device that is the subject of the invention.

Background of the Invention

In the field of anastomoses between body ducts, a first solution consists of directly connecting the ducts with the aid of manual surgical sutures. This solution has the sole advantage of not requiring any devices. However, the time necessary for performing it is relatively long and the quality of the junction depends on the dexterity of the practitioner in connecting two flexible ducts.

Another solution consists of utilizing a tubular prosthesis in the form of a sleeve whose two ends are intubed respectively in the two ducts to be connected with means provided for interlocking the intubed parts of the prosthesis and the end portions of said ducts.

~~Through document~~ Document WO 98/19631 ~~we know of~~ discloses an anastomosis device of the above type composed of a prosthesis formed from an expandable mesh structure whose intubed extremities in the ducts to be joined are equipped with means for anchoring them to the end portions of said ducts. For that purpose, each end of the prosthesis is composed of a special auto-expandable structure equipped with radial projections designed to penetrate the tissue of the ducts in order to prevent any slippage between said ducts and the prosthesis.

Such a device is not completely satisfactory. Firstly, because it requires that a special prosthesis be made since it incorporates distinctive structures at each extremity. Secondly, because the prosthesis cannot be set in place with the aid of a balloon catheter and the intubed parts of the prosthesis are pressed against the end portions of the ducts simply by auto-expansion, this technique does not assure a truly firm and impervious anchoring.

Additionally, ~~we also know through~~ document US 4,214,587 [[of]] discloses a two-vessel anastomosis device assisted by a radially resilient cylindrical spring equipped externally with barbs. This component has to be compressed to reduce its diameter in order for it to be introduced into the end portion of the duct to be anastomosed. Once released, it expands to assume its nominal diameter.

In addition, there is the disadvantage of a means of anchoring that is not guaranteed to be truly firm and impervious as in the preceding case, with the annular component ceasing to expand while the intubed portion may not be pressed completely against the end part of the duct to be joined. ~~; such~~ Such a component is necessarily dimensioned for an area of very reduced diameters in ducts to be anastomosed, thus necessitating the creation of a range of annular components of various diameters and a precise choice of the most suitable component for each anastomosis.

Finally, ~~through~~ documents US 5,931,842 and WO 98/19634~~, we know of~~ disclose systems intended to create anastomoses, but within the specific framework of cardiac bypasses, that is, end-side anastomosis assisted by expandable rings equipped externally with barbs, but with no details given as to the structure of the ring and arrangement of the barbs.

The aim of the present invention is to overcome the disadvantages of the known anastomosis systems and, in particular, to offer a device specifically adapted to end-to-end anastomoses.

Summary of the Invention

For this purpose, the invention ~~has~~ is a device for connecting the previously intubed extremities of a body duct with an approximately tubular prosthesis, ~~characterized by its being composed of~~ comprising a sleeve of mesh or analogous material, deformable by the use of a balloon catheter and capable of radial expansion between a stable minimal-diameter configuration and a final after-expansion configuration that is also stable, said

sleeve being equipped on each end with a series of fixation barbs for the portions covered by the sleeve, aligned at regular intervals, and encircling it radially. Said barbs present a hemostatic profile comprised of a circular base section extending to a trihedral end portion.

According to a preferred method of manufacture, the expandable sleeve ~~is composed~~ comprising of a steel cylinder with openwork diamond-shaped cutouts and the barbs are added and set by soldering or gluing at the intersections of the sides of said diamond-shapes.

According to another characteristic of the invention device, said sleeve is capable of expanding in a diameter ratio during fixation based on an initial diameter greater than 2.

According to a preferential method of manufacture, the ~~beyond end~~ immediate portion of the sleeve is also equipped with fixation barbs. Preferably, the barbs encircling the ends of the sleeve are straight and the other barbs are slightly curved with their points oriented toward one end or the other of the sleeve or randomly in any other direction.

The invention applies to joining an extremity of a prosthesis with the end portion of a body duct such as an artery of between 6 mm and 30 mm in diameter, but it also applies to the junction between two body ducts via a prosthesis whose two extremities are intubed in the end portions of the two ducts to be joined.

Brief Description of the Drawings

Other characteristics and advantages will emerge from the description that follows of a method of implementation of the invention, a description given solely as an example with reference to the annexed drawings, where:

Figure 1A is a perspective view of one method of making the connecting device of the invention in its minimum diameter configuration.[[,]]

Figure 1B shows the device of Figure 1A opened out to its maximum diameter configuration.[[,]]

Figure 2A is an upright view of a barb.[[,]]

Figure 2B illustrates the trihedral profile of the tip of the barb in Figure 2A.[[,]]

Figure 3 is a view showing the fixation of a prosthesis on a body duct with the aid of the connecting device of the invention.[[,]]

Figure 4 is a diagram illustrating the setting in place and fixation of a first body duct at a first end of a prosthesis.[[,]]

Figure 5 is a diagram illustrating the setting in place and fixation of a second body duct at the second end of the prosthesis.[[and]]

Figure 6 illustrates the application of the procedure for setting devices in place according to the invention on a forked prosthesis.

Detailed Description of the Drawings

As shown in ~~Figure~~ Fig. 3, the invention device can assure the connection between a prosthesis 10 and a body duct 12 in which one of the ends of the prosthesis 10 is intubed. This connecting device, intended for vascular ducts in particular, may be adapted for any other body duct in which a prosthesis can be intubed.

The prosthesis adapted to the body duct which is, in general, essentially tubular, is not described in more detail because it is familiar to professionals. According to a known method of manufacture, this prosthesis is most often made of DACRON7. It may be a straight tubular prosthesis or one forked in a Y shape.

According to the invention, the connecting device 14 between the prosthesis 10 and the body duct 12 is comprised of an expandable sleeve 16 arranged on the inside of the prosthesis made according to the method shown in ~~Figures~~ Figs. 1A and 1B. ~~Figure~~ Fig. 1A shows in diagram form a tubular sleeve 16 of openwork steel in its minimum diameter configuration, that is, as it is after its manufacture, and ready to use.

For example, the sleeve 16 is created by laser cutouts from a steel tube with a suitably thick wall of several tenths of a millimeter, is 8 mm in diameter and has a length of 24 mm. The cutouts are diamond-shaped so as to create an evenly meshed structure whose branches 18 separate the diamonds 20, by way of illustration, by a length of several millimeters: for example 4 mm for a width of the order of a few tenths of a millimeter. It should be noted that ~~Figures~~ Figs. 1A and 1B simply show the overall structure of the sleeve 16 and that the dimensional ratios indicated above are not those in the drawings.

According to the invention, on the two ends of the sleeve 16, fixation barbs 22 are placed at regular intervals encircling it radially facing outward from the external surface of the sleeve. The barbs 22 are of steel and are fastened, for example, by soldering or gluing onto the end points 24 of the sleeve 16. The barbs 22 have a length of between 0.5 mm and 3 mm and are straight. Their profile is hemostatic and comprises a cylindrical base 26 with a diameter of the order of several tenths of a millimeter, extending to an end part 28

in the shape of a trihedron. As with the meshed structure, the barbs 22 of ~~Figures~~ Figs. 1A and 1B are not shown at their actual size.

Preferably, all the points 24 at the two ends of the sleeve 16 are equipped with barbs 22. The barbs 22 of the ends may be of a reduced height compared to that of the barbs of the intermediate area. In fact, when the length of the sleeve 16 is greater than the length of the covered intubed portions, the end portions of the sleeve have a single wall to penetrate and so the barbs in these areas may be of a reduced height, having less wall thickness to penetrate than the other barbs of the sleeve.

On the external surface of the sleeve 16 defined between the two rings of end barbs 22, using the method of manufacture shown, barbs 22′ are also implanted at the intersections of the branches 18 of the mesh structure, more specifically, only at some intersections.

A circular ring 30 of barbs 22′ is arranged in the central area of the sleeve 16 at the rate of one barb for every two intersections. Between the central ring 30 and each end ring of barbs 22 another ring of barbs 22′ is arranged that is identical to the ring 30.

The distribution of barbs 22′ may or may not be even. Preferably, the barbs 22′ have the profile shown in ~~Figures~~ Figs. 2A and 2B, that is, a hemostatic profile of the type of barbs 22 with cylindrical base 32 extending to an end tip with a trihedral profile 34 (~~Figure~~ Fig. 2B).

Additionally, the end tip 34 is preferably curved in the direction of one end or the other of the sleeve 16 or in any other direction, the barbs 22′ preferably having various orientations and the incline of said end portions 34 being between 0 and 10[[°]]degrees, preferably approximately 5[[°]]degrees.

~~Figure~~ Fig. 1B represents the sleeve 16 of ~~Figure~~ Fig. 1A in the expanded state, the length of the mesh structure being reduced from 24 mm to 20 mm and the diameter going from 8 mm to 20 mm. Said structure is not elastic, has no shape memory and is dimensionally stable regardless of how far it is to be expanded, which will be done by way of a conventional inflatable balloon catheter at the time the invention connecting device is set in place. This~~; this~~ procedure will now be described with reference to ~~Figures~~ Figs. 3 to 5.

Utilization of such a connecting device is relatively simple and is described as shown in ~~Figure~~ Fig. 3. As is known, the end of the prosthesis 10 is intubed in the body duct 12 over a length of approximately 25 mm. The connecting device 14, very simply

diagrammed in ~~Figure~~ Fig. 3, is arranged in the interior of the prosthesis 10 to the right of the covered area of the body duct 12 and the prosthesis 10. When the sleeve 16 is expanded, the barbs 22, 22′ perforate both the prosthesis and the body duct so as to assure the joining of the two components.

The invention also applies to the anastomosis of two body ducts via a prosthesis 10 and 12.2 whose two ends are intubed in the end portions of said ducts. As illustrated by ~~Figures~~ Figs. 4 and 5, the connecting device is composed of two joining devices 14-1 and 14-2 composed, for example, by a sleeve 16 of the type in ~~Figure~~ Fig. 1, arranged respectively at each end inside the prosthesis 10.

Another objective of the invention is the setting in place of the connecting devices. For that purpose, a first end of the prosthesis 10 is intubed in the body duct 12.1. The first connecting device 14.1 is introduced into the interior of the prosthesis 10 through the second end and set in place as illustrated by ~~Figure~~ Fig. 4 with the aid of an inflatable balloon 36 attached to the catheter 38 for placement in the usual manner.

Then, according to the invention, the second end of the prosthesis 10 is intubed in the second body duct 12.2, and the second connecting device 14.2 (~~Figure~~ Fig. 5) is introduced through an orifice 40 arranged on the prosthesis 10 and, after being set in place, is re-closed by manual suture stitches. Thanks to the use of the connecting device of the invention, required operating times are reduced, permitting a reduction in mortality risk.

In ~~Figure~~ Fig. 6, a prosthesis divided in a Y shape 10′ is shown whose first end is intubed in a first body duct 12′-1 and fixated with the aid of a first sleeve 14′-1 according to the invention with the aid of the catheter 38 introduced into the prosthesis 10′ through one of the divided ends. The two divided ends of the prosthesis 10′ are intubed in two other body ducts 12′-2 and 12′-3 and fixed with the aid of two other sleeves 14′-2 and 14′-3 which are successively put in place as illustrated in ~~Figure~~ Fig. 5 by the introduction of the catheter 38 equipped with the balloon 36 over which the fixation sleeve (14′-2, 14′-3) is slipped through an orifice 40′ which will later be re-closed.

Due to the fact that the sleeve 16 can expand within a significant range of diameters, the ratio between the final, in situ, diameter of the sleeve and the initial diameter being advantageously greater than 2, and because its final state is stable since the sleeve does not retract once the placement balloon has been deflated, the sleeve 16 is

effectively squeezed against the intubed portions in question that is both impermeable and firm thanks to the fixation barbs 22, 22′ of said intubed portions.

Furthermore, the capability of the sleeve 16 to expand to varying sizes allows it, by way of a single-size sleeve, to be used for anastomoses, for example, of vessels whose diameters may vary over an extended range, for example, arteries, with a diameter of between 6 and 30 mm. Of course, however, depending on the applications, sleeves 16 may be made in different sizes and with barbs 22, 22′ of different shapes and dimensions and distributed in different ways on the sleeve.